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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,234	07/06/2000	JOHN D. STEEVES	MBM1200	3942

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1646	15

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,234	STEEVES ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6,16-18,29,30,32,35,37,39,41,42,45-50 and 52-54* is/are pending in the application.

4a) Of the above claim(s) *2,4,6,16-18,29,30,32 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46, 48, 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Claims 36, 38, 40, 43, 44 and 51 have been cancelled and claims 46, 48 and 49 have been amended as requested in the amendment of Paper No. 13, filed on November 08, 2002. Claims 2, 4, 6, 16-18, 29, 30, 32, 35, 37, 39, 41, 42, 45-50 and 52-54 are pending in the instant application.

Claims 2, 4, 6, 16-18, 29, 30, 32 and 35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11. Claims 37, 39, 41, 42, 45, 47, 50 and 52-54 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention elected by original presentation, see section 2 of Paper No. 12.

Claims 46, 48 and 49 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on November 08, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 46, 48 and 49, as amended, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record as applied to claims 36, 38, 43, 44, 46 and 48 in sections 8 and 9 of Paper No. 12 and the reasons that follow.

Claims 46, 48 and 49, as amended, are broadly drawn to a method for promoting neuron repair or regeneration in a human subject by transient demyelination by administration of a therapeutically effective amount of a composition of complement-fixing antibodies and complement proteins. The instant specification describes the principle of the invention and provides the description of experiments on rats having spinal transection treated with serum complement along with a complement-fixing antibody administered by direct intraspinal infusion. The instant specification fails to provide any guidance on how to practice the claimed method in human subjects, gives no information about the route and duration of administration, as well as quantity and ratio of the composition to be administered, or how to evaluate the results of the claimed method, thereby requiring undue experimentation to discover how to make and use Applicant's invention, as currently claimed.

Applicant submits that "a working example is not required to enable the breadth of the pending claims" (page 6, second paragraph of the Response). This has not been found to be persuasive because the claimed method lies in the field of treating neuron regeneration by administration of immunologically active proteins and antibodies, and this art is generally considered to be unpredictable. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) the court held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while

unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved".

The instant specification clearly fails to supply the guidance that would be needed by a routine practitioner to extrapolate data obtained from experiments on rodent model with surgical spinal transection and exercise the same method in a human subject having a nervous system dysfunction, which by broadest reasonable interpretation would include dysfunction due to trauma, degeneration, cancer, infectious diseases, intoxication and most of psychiatric conditions. Applicant points to pages 28-30 of the instant specification as support for preparation and administration of the composition comprising complement-fixing antibodies and complement proteins (page 6, last paragraph of the Response). However, the text of the above noted passages only provides exemplary typical range of concentrations and a statement that ""[t]he exact ratio of antibody to complement will vary depending on the circumstances" and "the particular concentration of antibody administered will vary with the particular dysfunction

and its severity" (page 28, lines 12-17 of the instant specification). Thus, provided only with a general range of concentrations of a composition comprising an antibody and a complement protein, one skilled in the art clearly would have to resort to substantial amount of undue experimentation in order to establish "a therapeutically effective amount of a composition", as well as regime of administration. The standard of an enabling disclosure is not the ability to make and test if the invention worked but one of the ability to make and use with a reasonable expectation of success. In the instant case, taking into consideration that administration of anti-myelin antibodies in combination with complement proteins causes demyelination of nervous tissue, a potentially serious pathological condition, a skilled practitioner needs to know precise protocol in order to practice the claimed invention, and such protocol is not supplied by the instant specification. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that: "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

6. Claims 46-49 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 46 is indefinite for being incomplete for omitting essential steps, such omission amounting to a gap between the steps for reasons of record in section 11 of Paper No. 12. See MPEP § 2172.01. Applicant argues that "[t]o promote neuron regeneration, in accordance with the invention, it is not necessary to carry out an indicating step [...]. Moreover, nowhere is it described in the specification that the step of indicating regeneration is necessary to practice the invention" (page 8, first paragraph of the Response). This has not been found to be persuasive because any method has a goal, steps to achieve that goal and a step, which indicates such achievement. In the instant case, the omitted step is the step that indicates the induction of promotion of neuron repair or regeneration (claim 46). The fact that the instant specification clearly fails to describe this step leads to the lack of enablement for one skilled in the art to practice the claimed invention, see reasons of record explained earlier in section 5 of the instant office action.

8. Claims 48 and 49 are indefinite for being dependent from the indefinite claim.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
January 21, 2003